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Case Report

Use of 'Guideliner' catheter to overcome failure of delivery of Absorb™ Bioresorbable Vascular Scaffold in calcified tortuous coronary lesions: Technical considerations in 'Real World Patients'

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ABSTRACT

In our series of 177 real world patients (223 lesions) who underwent Absorb Bioresorbable Vascular Scaffold (BVS) implantation, 78 lesions were calcified and tortuous lesions. In four of these, despite adequate lesion bed preparation, appropriate guiding catheter support and use of buddy wires, the BVS failed to track through the proximal calcified and tortuous coronary anatomy (CTCA). "Guide Liner" catheter (GLC) had to be finally used to resuccessfully deliver and implant BVS to the lesion site.

We report for the first time four cases of use of guideliner catheter to successfully overcome failed delivery of BVS to the lesion site through proximal CTCA, calcified and tortuous coronary artery (CTCA) lesions treated with Absorb™ BVS. Because the BVS is a large profile device, certain difficulties were encountered in delivering it through the GLC, which were finally overcome. We have therefore discussed the 'lessons and learnt' and "salient practice points" to enable successful delivery of BVS through the GLC.

1. Introduction

The Absorb™ Bioresorbable Vascular Scaffold (BVS) [Abbott Vascular, Santa Clara, USA] represents a fascinating advancement in stent technology for treatment of significant coronary stenosis with the benefits of 'best in class' metallic drug eluting stents (DES) in the short term and without leaving behind a permanent metallic implant in the long term. Based on the first in man studies,[1] its subsequent approval in many countries has lead to its increasing use in 'real world' patients with complex coronary artery disease, which had been excluded from the previous studies. Calcified, tortuous coronary arteries (CTCA) and lesions pose a

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challenge to the delivery and implantation of the BVS, because of its larger profile (the 2.5 mm and 3.0 mm diameter BVS has a crossing profile of ≤0.060″ and the 3.5 mm diameter; BVS has a crossing profile of ≤0.065″). Additionally if there is a failure to deliver the BVS across the lesion, then the high profile 'invisible device' would have to be withdrawn into the Guide Catheter (GC) with a risk of device dislodgement. Once withdrawn, a new BVS has to be taken for the second attempt as per the Instruction for Use (IFU Absorb, Abbott Vascular, Santa Clara, USA). Various 'tricks', which have been well described to overcome failure of stent delivery, like better GC support and 'deep' intubation, 'extra support' wires and 'buddy wires', may also occasionally fail to deliver a BVS across difficult CTCA. From Jan 2013 to Sep 2013, out of 177 "real world" lesion treated with BVS, 78 lesions were calcified or/and had proximal CTCA. Of these the BVS failed to deliver in four cases despite all efforts and tricks outlined above. The use of the GuideLiner™ catheter (GLC) [Vascular Solutions, Minneapolis, USA] a rapid exchange, coaxial, guide catheter extension device[2] finally enabled successful implantation of BVS. As the BVS is a large profile device, certain problems were encountered during its use with GLC. We therefore, describe for the first time the technical considerations for the use of GLC to deliver Absorb through the series of four cases. These observations would be even more vital when delivering BVS through 6F GC via radial route in CTCA.

2. Case reports

2.1. *Case I*

A 72-year-old gentleman with Diabetes and hypertension presented with exertional angina of 3 months duration. Coronary angiogram (CAG) revealed single vessel 80% calcified mid-Left anterior descending artery (LAD) stenosis. The proximal LAD was also calcified and had two bends (Fig. 1a and b.) Rotational atherectomy of LAD was performed with a 1.5 mm burr. The lesion was then fully pre-dilated with 2.5 × 12 mm non-compliant (NC) balloon to 24 atm with no residual stenosis. Stenting of LAD was attempted using a 2.5 × 28 mm BVS through a 7F extra back up GC and over an All Star™ extra support wire (Abbott Vascular, Santa Clara, USA) and "Buddy Wire". The BVS could not be delivered to the lesion site and was withdrawn. A 7F (6 in 7) GLC was then gently advanced into the LAD over an inflated balloon for approximately 3 cm across the proximal CTCA. A new 2.5 × 28 mm BVS was then advanced through the proximal metallic collar of GLC under direct fluro vision. The BVS would not enter through the proximal collar of GLC into its catheter extension due to the guide wire bias or intertwining, especially as the collar lay in the curved segment of the arch of the aorta. Because the GLC had already been advanced through the proximal CTCA of LAD, it was preferred not to withdraw the GLC to get the collar to a straight segment

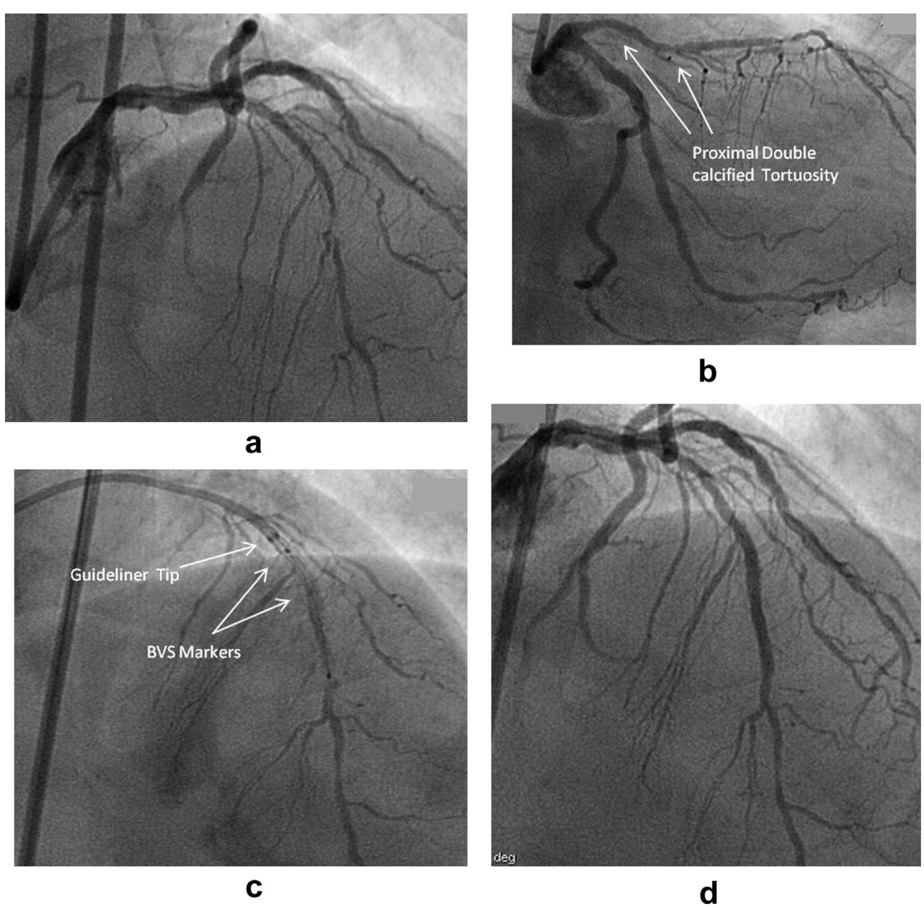

Fig. 1 – Case 1: (a) and (b) left coronary angiogram in AP cranial and RAO caudal views showing proximal double calcified tortuosity, (c) use of Guideliner catheter for BVS deployment, and (d) final result.

Table 1

Case/ Fig. no.	Vessel (v)| size (mm) | lesion stenosis % (visual estimate)	GC shape and size	Lesion preparation	Size of BVS	Techniques used to deliver BVS	No. of failed attempts to deliver BVS	Size of GL	Technique used to deep intubate the GLC	Problems faced during delivery of BVS through GLC	Technical indications while using GLC	Final post dilatation	Complication	Follow up
Case 1 (Fig. 1)	Mid-LAD | 2.5 mm | 80%	7F XB	• Rotabaltor 1.5 mm burr • Pre-dil.: 2.5 mm NC balloon at 24 atm	2.5 × 28 mm	• Buddy wire: failed • Deep intubation GC • Support wire	One	7F (6 in 7)	Deep intubated over inflated balloon	Contrast injection through wedged deep intubated GL caused bradycardia/ transient asystole	Avoid forceful contrast injection, during deep intubation of GL	2.75 × 12 mm NC balloon at 24 atm	None	Well at 9-months
Case 2 (Fig. 2)	Mid-LAD | 3.0 mm |80%	7F XB	Pre-dil.: 2.5 mm NC balloon at 24 atm and 3.0 mm NC balloon at 24 atm	3.0 × 18 mm (two BVS maker to marker overlap distal to proximal)	• Deep intubation GC • Buddy wire • Balloon upsizing HP pre-dilatation	Two	7F (6 in 7)	Deep intubated over balloon shaft	• Difficulty in entering GLC through proximal metallic collar • Proximal dissection	• Pulled GC back by 5 cm to straighten GL in aortic arch. • 3.0 × 12 mm Xience™ stent to cover proximal edge dissection	3.0 × 12 mm NC balloon at 24 atm	Proximal LAD dissection treated with 3.0 × 12 mm Xience™ (Abbott Vascular, Santa Clara, USA)	Well at 7-months
Case 3 (Fig. 3)	1	7F JR 3.5	3.0 mm NC balloon at 20 atm	3.0 × 18 mm	• Deep Intubation GC • Buddy wire • Support wire	Two	6F (5 in 6)	Deep intubated over the two wires	3.0 × 18 mm BVS would not enter through the metallic collar of GL into the extension tube	GL withdrawn out of the GC and BVS preloaded and the combination reinserted and advanced	3.25 × 12 mm NC balloon at 24 atm	None	Well at 5-months
Case 4 (Fig. 4)	Mid-RCA | 3.0 mm | 70%	7F JR 3.5	3.0 mm NC balloon at 20 atm	3.0 × 18 mm	• Deep intubation GC • Buddy wire • Support wire	Two	7F (5 in 6)	Deep intubated over single support wire	3.0 × 18 mm BVS would not enter through the metallic collar of GL into the extension tube	GL withdrawn till the metallic collar lay in straight descending aorta to make the entry of BVS in GL coaxial.	3.25 × 12 mm NC balloon at 26 atm	None	Well at 3-months

of the aorta. So, the GC was withdrawn leaving the GLC tip in the LAD. This led to straightening of the proximal segment of GLC and realignment of the wire at the GLC metallic collar enabling the BVS to cross the collar and enter to GLC extension tube. The BVS was then successfully delivered across the lesion through the deep intubated GLC and post dilated with 2.75 × 12 mm NC balloon upto 20 atm (Fig. 1c and d). The procedure was successful and the patient was discharged with no complications and remains well at 9-months follow up.

2.2. *Case 2, 3, and 4*

The salient angiographic, clinical and procedural difficulties and solutions are outlined in Table 1.

3. Discussion

The benefits of BVS to treat complex lesion subsets especially calcified lesions remain to be proven and may be speculative. Yet, as its use expands to more complex anatomy in 'real world' patients, CTCA lesions are regularly encountered. Optimal implantation and expansion of BVS in calcified lesion require adequate lesion and vascular bed preparation with high pressure balloon dilatations and occasionally the use of cutting balloons, scoring balloons or rotational atherectomy. Of equal importance is the vessel tortuousity and calcification proximal to the lesion as this may provide extreme resistance and prevent delivery of 'high profile' BVS to the lesion. Hence, appropriate evaluation of the proximal vessel for tortuousity and calcification, prior to the delivery of BVS, has become more important than with metallic stents to achieve a successful implantation.

Following the approval of BVS in India in December 2012 to date we have used 223 BVS in 177 patients of which 78 have been CTCA lesions. We have had to resort to the use of GLC in four patients, where all attempts to deliver BVS failed. The use of GLC to deliver BVS and problems encountered has not been reported in literature before. Our cases provide the following important and first time technical insights and learnings specific to the delivery of BVS through GLC:

A) 7F GL (6 in 7F) internal diameter: 0.062″ – All sizes of BVS can be delivered through a 7F GLC.

The 3.5 mm BVS is tight fit .The entry of BVS through the proximal metallic collar of GLC into the guide extension

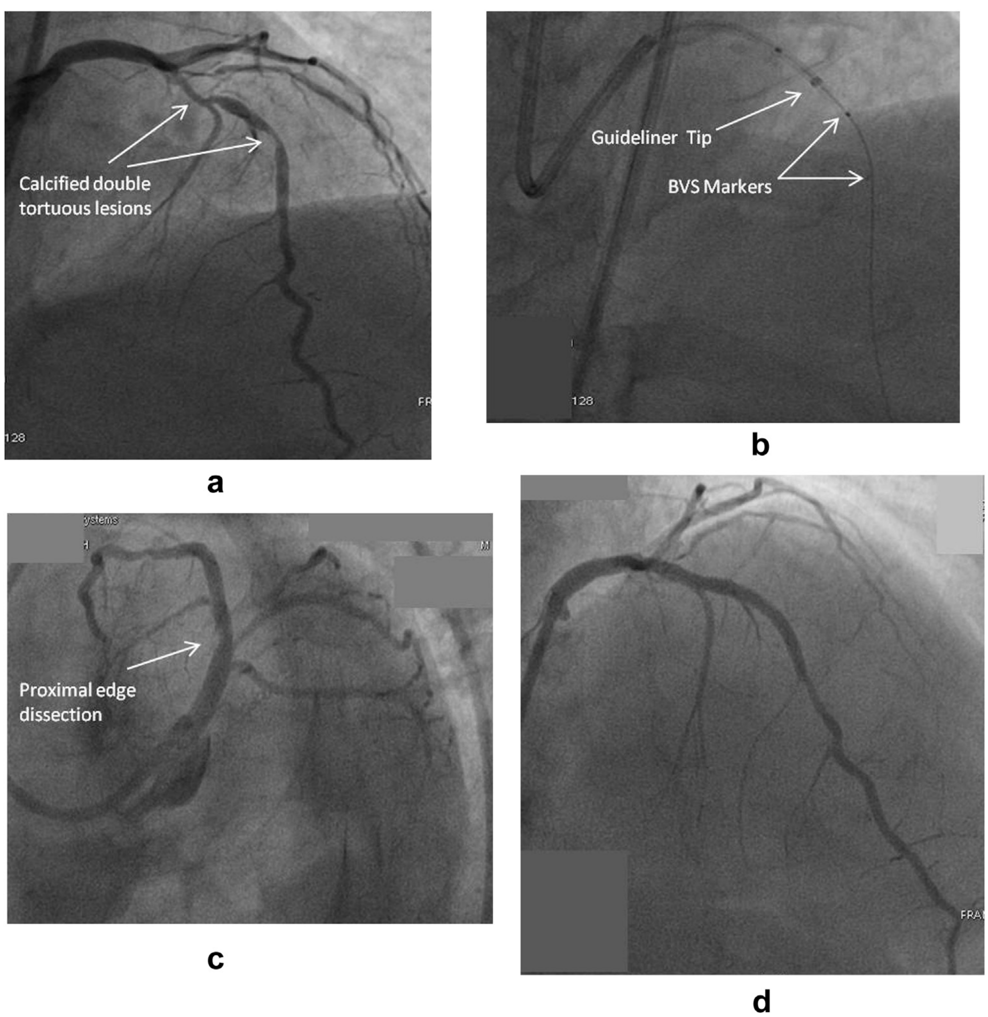

Fig. 2 – Case 2: (a) AP cranial view showing LAD/D1 bifurcation lesion, (b) use of Guideliner for BVS deployment, (c) LAO caudal view showing proximal edge dissection, and (d) final result.

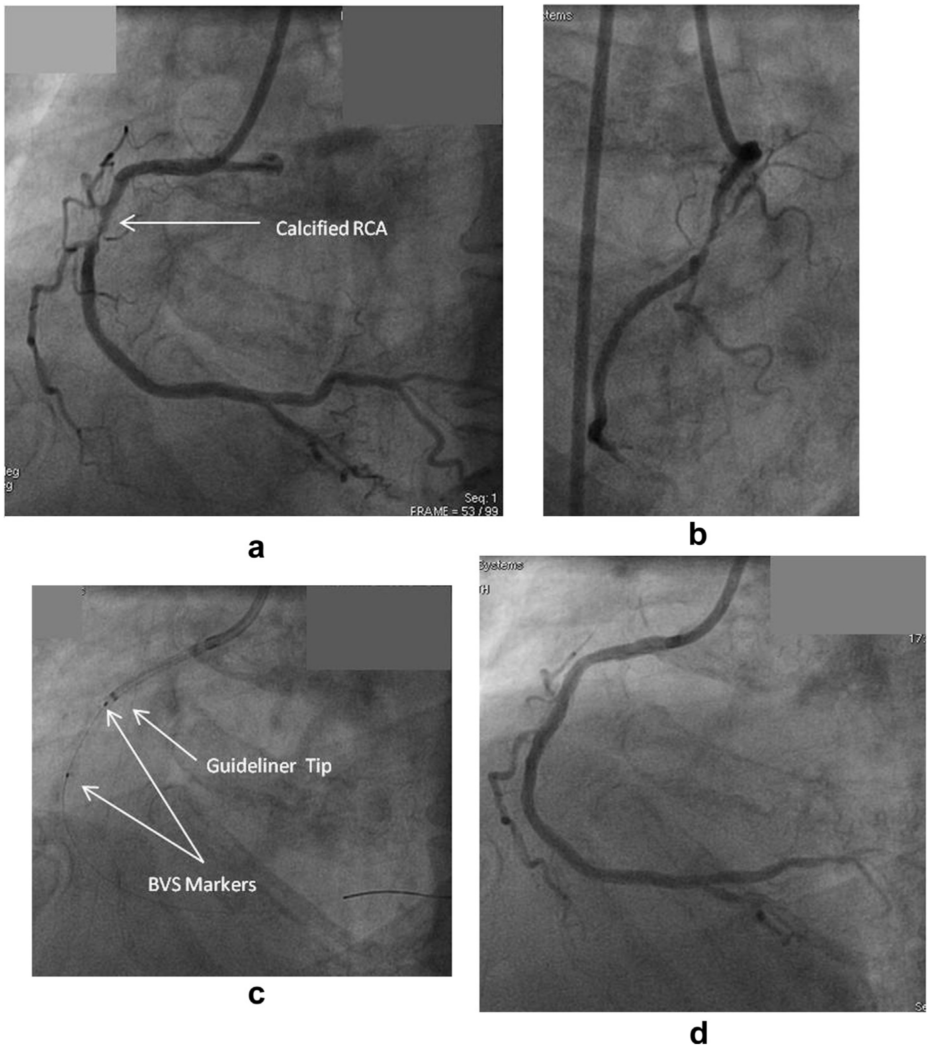

Fig. 3 – Case 3: (a) and (b): LAO and RAO view showing calcified lesion in mid-RCA, (c) use of Guideliner for BVS deployment, and (d) final result.

tube should be performed under fluro vision and should be extremely gentle; this is where the large profile BVS especially the 3.5 mm BVS encounters most resistance.

B) In some cases, the BVS may not go through the proximal collar into the distal 20 cm extension as this lies on the curve of the aortic arch and there may be a guide wire bias or intertwining. Care should be taken not to force the BVS through the proximal collar but to withdraw the GLC back into the GC so that the proximal collar lies in the straighter segment of thoracic aorta thus making it more coaxial to allow easier entry of BVS through the proximal collar of GLC (Case no. 4). Alternatively, leaving the GL deeply intubated, the GC can be withdrawn out of the coronary artery ostium for 4–5 cm which straightens the proximal segment of GLC and alters the guide wire bias at the metallic collar enabling the BVS to enter into the GLC extension tube (Case 1).

C) 6F GLC (5 in 6F) internal diameter: 0.056″. The 2.5 mm and 3.0 mm diameter BVS are a 'tight fit' and hence will not enter through the proximal 'metallic collar' while the GLC is in the GC. They can be 'preloaded' into the GLC extension tube outside, prior to entry into the guiding catheter (GC) and the combination can then be advanced to the distal end of the GC. From here the GLC is first advanced deep into the vessel across proximal tortuousities and then the BVS is advanced to deliver it to the lesion as was done in our case no. 3.

A 3.5 mm BVS cannot be preloaded into a 6F GLC. This information is extremely important as Radial route using 6F GC is becoming an increasingly popular route for coronary intervention.

We believe that the GLC is an important and extremely useful device to enable safe and successful delivery of BVS in CTCA. Keeping in mind that one would like to avoid the withdrawal of this 'invisible' stent, which should not be reintroduced once withdrawn out of GC (as per IFU), it is important to have a successful delivery of BVS to the lesion

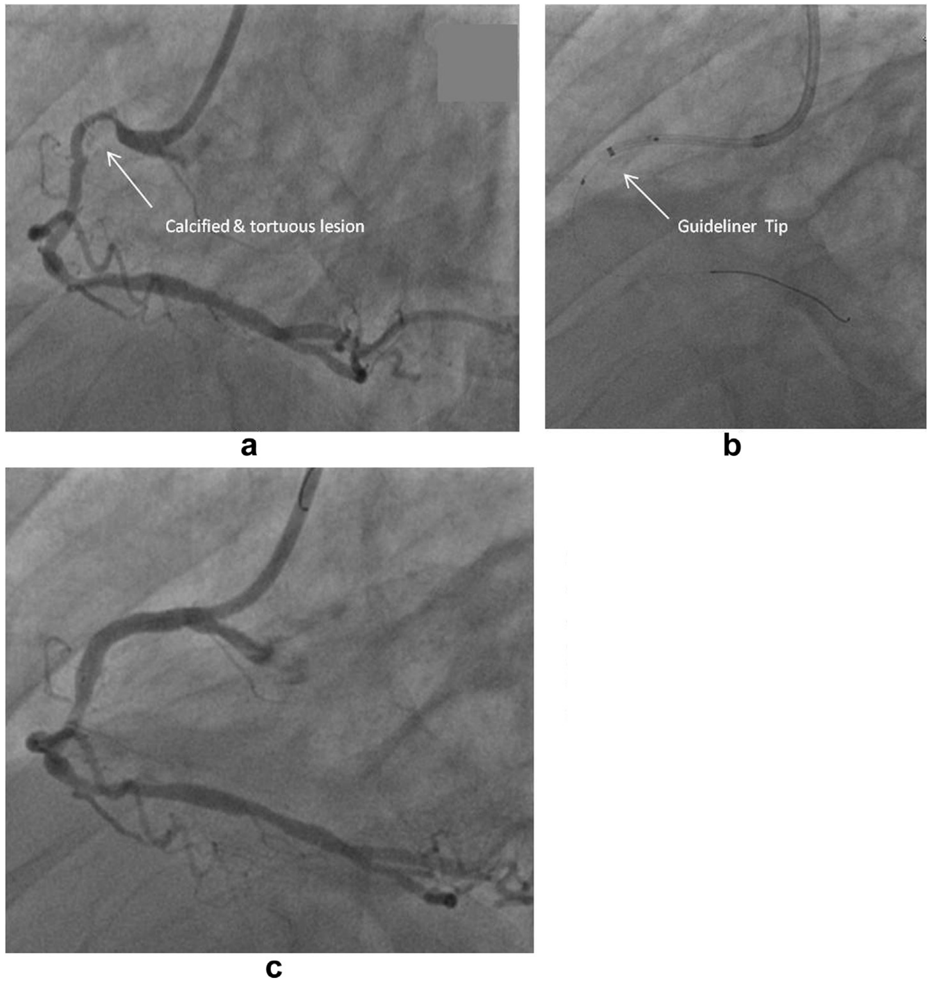

Fig. 4 – Case 4: (a) LAO view showing calcified and tortuous lesion in proximal RCA, (b) use of Guideliner for BVS deployment, and (c) final result.

site in the first attempt. For this, careful evaluation of calcification and tortuosity of the vessel before the lesions and at the lesion and upfront use of GLC for difficult anatomies keeping the above technical considerations in mind could lead to increasing successful implantation of BVS in the 'real life' patients with CTCA. Whether BVS will have the same potential advantages and results in the long term in calcified lesions compared with non-calcified lesions remains to be proven and is speculative.

4. Conclusions

The delivery of BVS through calcified tortuous coronary artery may be difficult. GLC may be helpful for BVS delivery in such lesions where other maneuvers have failed. However, as BVS has different profile and performance characteristics compared with a metallic stent, certain technical consideration described in the paper need to be kept in mind to enable successful delivery and implantation.

Conflicts of interest

All authors have none to declare.

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